

REMARKS

Applicants would like to thank Examiner Daniel Kolker for the courtesy of the telephonic interview on September 11, 2007 to the undersigned attorney and Applicants' attorney Lily Rin-Laures. Applicant wishes to thank the Examiner for his helpful suggestions. As discussed, Applicants are filing an RCE herewith to expedite prosecution.

Claims 17-19, 21, 22 and 58-62 are pending in the application.

I. Summary of Interview of September 11, 2007 pursuant to MPEP §713.04 and 37 CFR §1.133

During the interview, the outstanding art rejections and the proposed amendments of claim 17 were discussed. The Examiner indicated that the claims do not read on full-length RAP. No final claim language was agreed upon.

II. Support for the Amendment to the Claims

Support for the amendment to the claims can be found throughout the specification. For example, page 37, line 26, to page 39, line 17, describes RAP polypeptides, having the amino acid sequence 221-323 and polypeptide 80% homologous thereto, and retaining the activity of full-length RAP. Page 6, lines 27-31, describes administration of megalin ligands conjugated to an active agent for delivery of the agent across the blood-brain barrier (BBB). Claims 17 and 19 have been amended to include sequence identifiers.

The amendment includes no new matter.

III. The rejection under 35 U.S.C. §102

The rejection of claims 17-19, 21 and 58-59 under 35 U.S.C. §102(e) over Beliveau et al., U.S. Patent Application Publication No. 2003/0129186 and under 35 U.S.C. §102(a) over Beliveau et al., Int'l Publication No. WO 03/009815 may properly be withdrawn because neither of these cited references discloses all elements of the claims.

The claims have been amended for clarity and are directed to a method of delivering an agent to the central nervous system comprising administering a conjugate comprising an agent and a RAP polypeptide consisting of an amino acid sequence 80% identical to amino acids 221-323, which retains megalin-binding activity. As agreed during the interview, the claims do not read on a full-length RAP protein that may comprise the recited amino acids. Neither Beliveau reference teaches the particular RAP polypeptide domain 3 sequence recited in the claims. Moreover, neither reference teaches that domain 3 fragments of RAP are desirable delivery vehicles for blood-brain transport or that one should administer agents conjugated to a megalin-binding RAP polypeptide as claimed.

The Examiner also rejected claims 17-18 under 35 USC §102(b) as assertedly anticipated by Lenting (WO 00/28021), as evidenced by Lenting U.S. Patent 6,919,311.

As stated above, the claims are directed to a conjugate comprising a megalin-binding RAP polypeptide that consists of an amino acid sequence 80% identical to amino acids 221-323 of RAP and do not read on a full-length RAP protein that may comprise the recited amino acids. Lenting discloses a conjugate comprising full-length RAP and glutathione-S -transferase (GST). Lenting neither discloses nor suggests the particular RAP domain 3 polypeptide set out in the claims, nor suggests that RAP or megalin are useful to mediate transport across the BBB. Therefore, Lenting does not disclose all the elements of the claims.

For these reasons, the rejections of the claims as assertedly anticipated by the cited art should properly be withdrawn.

IV. The rejection under 35 U.S.C. §103(a)

The rejection of all claims under 35 U.S.C. 103(a) over Beliveau, U.S. Patent Application Publication No. 2003/0129186, or alternatively over Beliveau, Int'l Publication No.

WO 03/009815, in combination with Perez-Navarro (J Neurochem 75:2190-99, 2000), may properly be withdrawn because none of the references, even in combination, disclose or suggest all elements of the claims.

The Examiner cites Perez-Navarro as teaching use of BDNF for Huntington's disease. Perez-Navarro neither discloses nor suggests the RAP polypeptide recited in the claims, nor suggests that RAP or megalin are useful to mediate transport across the BBB. The primary references fail to disclose all elements of the claims for the reasons noted above, and Perez-Navarro adds no relevant disclosure with respect to RAP.

For all of these reasons, the rejections for asserted obviousness over the cited art should properly be withdrawn.

V. Double Patenting

Applicants submit herewith a Terminal Disclaimer with respect to the subject matter of claims 3-6 and 14 that could issue from co-owned, co-pending patent application no. 11/202,566.

VI. Inventorship

Applicants acknowledge the Examiner's comments relating to inventorship with respect to the present application and co-owned, co-pending application no. 11/202,566. The two applications are currently commonly assigned, and were owned by the same entity at the time of invention

VII. Prior art made of record and not relied upon

In the interview of September 11, the Examiner asked that Applicants review the art cited the action, but not relied upon (see page 9 of the Action), and provide comments.

Applicants submit that the Examiner's summary of the cited art is correct, and that none of the

cited art teaches the use of a RAP polypeptide as recited in the present claims in a conjugate for administration to a mammal as claimed.

VIII. Conclusion

Applicants submit that the application is in condition for allowance and respectfully request notification of the same.

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Respectfully submitted,

By /Katherine L. Neville/
Katherine L. Neville
Registration No.: 53,379
MARSHALL, GERSTEIN & BORUN LLP
233 S. Wacker Drive, Suite 6300
Sears Tower
Chicago, Illinois 60606-6357
(312) 474-6300
Attorneys for Applicant